

Regimen Monograph

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A - Regimen Name

EXEM Regimen

Exemestane

Disease Site Breast**Intent** Adjuvant**Regimen Category** **Evidence-Informed :**

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

Rationale and Uses For the adjuvant treatment of operable breast cancer in postmenopausal patients with estrogen receptor-positive tumours who have completed two to three years of tamoxifen therapy*

*Aromatase inhibitors (AIs) have been used in the neoadjuvant setting in some clinical trials; AIs generally demonstrated higher breast conserving surgery rates with superior or similar response rates to tamoxifen. However, neoadjuvant AI use has not been approved by Health Canada .

Supplementary Public Funding [exemestane](#)
 ODB - General Benefit (exemestane) ([ODB Formulary](#))

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B - Drug Regimen**[exemestane](#)**

25 mg

PO

Daily

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Unless disease progression or unacceptable toxicity

Upfront treatment: For 5 years

Switch strategy: For 2-3 years (as a switch after 2-3 years of tamoxifen) for a total of 5 years of endocrine therapy

Extended adjuvant therapy: For 3-5 years, after completing 5 years of tamoxifen

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Antiemetic Regimen: Not applicable

Other Supportive Care:

- Assess patient's risk factors for osteoporosis and consider calcium and vitamin D supplements and bisphosphonates where appropriate. Refer patients to the [Bone Health During Cancer Treatment](#) pamphlet for more information.

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated.

Dosage with toxicity

Toxicity	Exemestane Dose
Myelosuppression	No adjustment required.
Severe cutaneous reactions or acute generalized exanthematus pustulosis (AGEP)	Discontinue permanently.

Hepatic Impairment

Although AUC is tripled in the presence of liver impairment (Child-Pugh C), adverse effects are not increased. No dosage adjustment is required.

Renal Impairment

Although AUC is tripled in the presence of severe renal impairment (CrCl < 30 mL/min), adverse effects are not increased. No dosage adjustment is required.

Dosage in the Elderly

No dosage adjustment is required.

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F - Adverse Effects

Refer to [exemestane](#) drug monograph(s) for additional details of adverse effects.

Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
<ul style="list-style-type: none"> • Estrogen deprivation symptoms • Musculoskeletal pain • Fatigue • ↑ LFTs (may be severe) • Alopecia • Headache • Insomnia • Hypertension • Dizziness 	<ul style="list-style-type: none"> • Cardiotoxicity • Arterial thromboembolism • Venous thromboembolism • Secondary malignancies • Osteoporosis/fractures • Hypersensitivity • Rash • GI ulcer • ↑ cholesterol

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G - Interactions

Refer to [exemestane](#) drug monograph(s) for additional details.

- Avoid concomitant use of estrogen-containing or estrogenic agents due to ↓ effect of exemestane.
- Monitor PT/INR of patients on warfarin switching from tamoxifen to exemestane due to possible INR level changes.

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H - Drug Administration and Special Precautions

Refer to [exemestane](#) drug monograph(s) for additional details.

Administration

- Tablets should be swallowed whole with a glass of water after a meal (to enhance absorption).
- Store tablets at room temperature (15-30°C).

Contraindications

- Patients with known hypersensitivity to exemestane or any of its components

Warning/Precautions

- Use is not recommended in pre-menopausal women*.
- Patients with pre-existing severe osteoporosis, a history of osteoporotic fracture or significant cardiac disorders were excluded from clinical trials in early breast cancer.
- Exemestane may increase risk of gastric ulcers especially in patients on NSAIDs and/or with a prior history.

**not receiving ovarian suppression*

Pregnancy and Lactation

- Exemestane is not recommended for use in pregnancy. Adequate contraception should be used by both sexes during treatment, and for at least **6 months** (general recommendation) after the last dose.
- Breastfeeding is not recommended during treatment.
- Fertility effects: Probable

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Recommended Clinical Monitoring

- Bone mineral density; Baseline and as clinically indicated
- Cholesterol and lipids evaluation; Baseline and as clinically indicated
- Clinical assessment of estrogen deprivation symptoms, fatigue, cardiovascular, musculoskeletal, thromboembolism, hypersensitivity, skin and GI effects; At each visit
- Grade toxicity using the current [NCI-CTCAE \(Common Terminology Criteria for Adverse Events\) version](#)

Suggested Clinical Monitoring

- CBC; Baseline and as clinically indicated
- Liver and renal function tests; Baseline and as clinically indicated
- INR for patients on warfarin (when switching from tamoxifen to exemestane); As clinically indicated

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J - Administrative Information

Outpatient prescription for home administration

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K - References

Coombes RC, Fall E, et al. A randomized trial of exemestane after two to three years of tamoxifen therapy in postmenopausal women with primary breast cancer. *New England Journal of Medicine*. 2004; 350 (11):1081-92.

Coombes RC, Kilburn LS, Snowdon CF, et al. Survival and safety of exemestane versus tamoxifen after 2-3 years' tamoxifen treatment (Intergroup Exemestane Study): a randomised controlled trial. *Lancet* 2007; 369(9561): 559-70.

Exemestane drug monograph. Ontario Health (Cancer Care Ontario).

Lønning PE, Geisler J, Krag LE, et al. Effects of exemestane administered for 2 years versus placebo on bone mineral density, bone biomarkers, and plasma lipids in patients with surgically resected early breast cancer. *J Clin Oncol* 2005; 23: 5126-37.

Mlineritsch B, Tausch C, Singer C, et al. Exemestane as primary systemic treatment for hormone receptor positive post-menopausal breast cancer patients: a phase II trial of the Austrian Breast and Colorectal Cancer Study Group (ABCSG-17). *Breast Cancer Res Treat* 2008;112(1):203-13.

Tubiana-Hulin M, Becette V, Bieche I, et al. Exemestane as neoadjuvant hormonotherapy for locally advanced breast cancer: results of a phase II trial. *Anticancer Res* 2007;27(4C):2689-96.

PEBC Advice Documents or Guidelines

- [Optimal Systemic Therapy for Early Female Breast Cancer](#)

November 2020 Updated adverse effects, interactions, drug administration, special precautions and monitoring sections

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Regimen Monographs

Refer to the [New Drug Funding Program](#) or [Ontario Public Drug Programs](#) websites for the most up-to-date public funding information.

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The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

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